

Message Text

UNCLASSIFIED

PAGE 01 STATE 085278

64

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-09 NEA-10 ISO-00 OES-06 /054 R

DRAFTED BY DHEW/FDA:JRWEINROTH, M D : AMS

APPROVED BY OES/APT/BMP WJWALSH, III

DHEW/OIH: MACODDING

EUR/EX:JCLARK INFO

EA/ROC: CWFREEMAN INFO

ARA/EX:KDACKERMAN INFO

EA/EX:RSCARRITT INFO

NEA/IRN:BMORTON INFO

----- 120619

P 082317Z APR 76

FM SECSTATE WASHDC

TO AMEMBASSY BUENOS AIRES PRIORITY PRIORITY

AMEMBASSY SANTIAGO PRIORITY

AMEMBASSY BOGOTA PRIORITY

AMEMBASSY SAN JOSE PRIORITY

AMEMBASSY SANTO DOMINGO PRIORITY

AMEMBASSY QUITO PRIORITY

AMEMBASSY SAN SALVADOR PRIORITY

AMEMBASSY GUATEMALA PRIORITY

AMEMBASSY PORT AU PRINCE PRIORITY

AMEMBASSY TEGUCIGALPA PRIORITY

AMEMBASSY TEHRAN PRIORITY

AMEMBASSY ROME PRIORITY

AMEMBASSY SEOUL PRIORITY

AMEMBASSY BEIRUT PRIORITY

AMEMBASSY MEXICO PRIORITY

AMEMBASSY MANAGUA PRIORITY

AMEMBASSY PANAMA PRIORITY

AMEMBASSY LIMA PRIORITY

AMEMBASSY MANILA PRIORITY

AMEMBASSY LISBON PRIORITY

AMEMBASSY MADRID PRIORITY

AMEMBASSY TAIPEI PRIORITY

AMEMBASSY BANGKOK PRIORITY

AMEMBASSY ANKARA PRIORITY

AMEMBASSY CARACAS PRIORITY

UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 085278

UNCLAS STATE 085278

E.O. 11652: N/A

TAGS:TW TH TU OGEN ETRD TBIO AR VE CI, CO, CS, DR, EC, ES,

SUBJECT: FDA ADVISORY - MANDATORY REQUIREMENT FOR
INSTALLATION OF RELIEF VALVE IN ALL ANESTHESIA MACHINES
EQUIPPED WITH STANDARD AND SIDE ARM VERNI-TROL VAPORIZERS
(RECALL T-071-6)

1. FDA ADVISES THAT:

PRODUCT INVOLVED: STANDARD AND SIDE ARM VERNI-TROL
VAPORIZERS - THE STANDARD VERNI-TROL VAPORIZER CAN ONLY
BE ORDERED AS PART OF AN ANESTHESIA MACHINE, WHILE THE
SIDE-ARM VERNI-TROL VAPORIZERS MAY BE INSTALLED ON ANY
ANESTHETIC MACHINE AND ARE IDENTIFIED IN THE FIRM'S
CATALOG BY TWO STOCK NUMBERS: 216-6356-880, 216-6356-882.

LOT NUMBERS: NO LOT NUMBERS OR MODEL NUMBERS ARE
ASSOCIATED WITH THESE VAPORIZERS.

MANUFACTURER/RECALLING FIRM:

OHIO MEDICAL PRODUCTS
DIVISION OF AIRCO, INC.
3030 AIRCO DRIVE
MADISON, WISCONSIN 53701

2. REASON FOR ADVISORY: THE FIRM IS MODIFYING ALL
ANESTHESIA MACHINES WHICH HAVE A VERNI-TROL OR SIDE-ARM
VERNI-TROL VAPORIZER BECAUSE FIELD REPORTS AND
LABORATORY TESTING HAVE INDICATED THAT, UNDER CERTAIN
CONDITIONS, HIGH PRESSURES IN THE BREATHING CIRCUIT
CAN CAUSE THE ANESTHETIC AGENT TO BACK UP INTO THE
FLOW METERS AND THE DELIVERY FLOW LINE TO THE PATIENT
IN ANESTHESIA MACHINES LACKING A PRESSURE RELIEF VALVE.
THIS POSSIBILITY REPRESENTS A POSSIBLE OR POTENTIAL
LIFE THREATENING HAZARD TO THE PATIENT. USERS OF THESE
UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 085278

VAPORIZERS WERE NOTIFIED BY LETTER DATED FEBRUARY 12, 1976
AND VALVES AND INSTALLATION INSTRUCTIONS WERE SENT TO
ALL FIELD REPRESENTATIVES.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES
TO DETERMINE IF THEY HAVE RECEIVED THE ADVISORY LETTER
FROM OHIO MEDICAL PRODUCTS REGARDING THE NECESSITY
FOR INSTALLATION OF PRESSURE RELIEF VALVES. ANY

QUESTIONS CONSIGNEES MAY HAVE REGARDING CORRECTIVE
ACTION SHOULD BE DIRECTED TO THE FIRM.

4. FOREIGN CONSIGNEES AS FOLLOWS:

LUTZ FERRANDO AND CIA
FLORIDA 240
BUENOS AIRES, ARGENTINA

SERVICIO NACIONAL DE SALUD
SANTIGO, CHILE

CLINICA CENTRAL SA
SAN ISIDRO 231
SANTIAGO, CHILE

HOSPITAL NAVAL DE TALCAHUANO
TALCAHUANO, CHILE

CLINICA PALERMO
BOGOTA, COLUMBIA

CLINICA CENTRAL DEL
QUINDIO DE ARMENIA
QUINDIO, COLOMBIA

DEPARTAMENTO DE CALDAS
MANIZALES, COLOMBIA

CLINICA EL ROSARIO
CALLE 62 CRA 41 NO. 62 5
UNCLASSIFIED

UNCLASSIFIED

PAGE 04 STATE 085278

MEDELLIN, COLOMBIA SA

CLINICA MINERVA SA
IBAGUE TOLIMA
COLOMBIA

SERVICIO DE SALUD
DEL MAGDALENA
SANTAMARTA, COLOMBIA

INSTITUTO COLOMBIAN
DE SEGUROS SOCIALES
AVENIDA 3A NORTE 24 N150
CALI VALLE, COLOMBIA

COMITE PRO-DAMNIFICADOS
MANAGUA
SAN JOSE, COSTA RICA

CLINICA SANTA RITA
SAN JOSE, COSTA RICA

CLINICA SANTO DOMINGO
SANTO DOMINGO
DOMINICAN REPUBLIC

CALMEST C POR A
AVE TIRADENTES
APARTADO 169 ZONA 2
SANTO DOMINGO, DOM. REP.

DEPARTAMENTO MEDICO DEL
SEGURO SOCIAL ECUATORIANO
CALLE FLORES NO. 732
QUITO, ECUADOR

MARCEL J. WOLFF
CALLE ARCE NO. 1219
SAN SALVADOR, EL SALVADOR

MINISTERIO DE SALUD
UNCLASSIFIED

UNCLASSIFIED

PAGE 05 STATE 085278

PUBLICA YAS
GUATEMALA, GUATEMALA

CELIN PAULEMON
NO. 54 RUE BONNIE FOI
PORT AU PRINCE, HAITI

GOBIERNO DE HONDURAS
HOSP MATERNO INFANTIL
TEGUCIGALPA, HONDURAS

IRAN BEHDASHT CO. LTD
P. O. BOX 12-1144
TEHRAN, IRAN

TEHERAN UNIVERSITY
BAHRAMI HOSPITAL
TEHRAN, IRAN

CORALMA SAS

VIA CORSICA 2-1
POST BOX N-773
16128 GENOA, ITALY

DONG RUNG MOOLSAN LTD.
I P O BOX 3022
SEOUL, KOREA

GOVT REPUBLIC KOREA
OFFICE OF SUPPLY
SEOUL, KOREA

ATCO MIDDLE EAST
P O BOX 5923
HAMRA ST - ELDORADO BLDG
BEIRUT, LEBANON

F. MAKHLOUF AND CO.
144 DAMASCUS AVE.
UNCLASSIFIED

UNCLASSIFIED

PAGE 06 STATE 085278

P. O. BOX 983
BEIRUT, LEBANON

REPRESENTACIONES
MEDICO TECHNICAS SA
MAZATLAN NO. 83-101
MEXICO DF MEXICO

ASOCIATION GINECO
OBSTETRICA HOSP. MEXICO
MEXICO DF MEXICO

INSTITUTO MEXICANO DEL
SEGURO SOCIAL
PASEO DE LA REFORMA 476
MEXICO DF MEXICO

SECRETARIA DE LA DEFENSA
NACIONAL
MEXICO DF
MEXICO

INSTITUTO DE SEGURIDAD
SERV SOCIALES DE LOS
TRABAJADORES DEL ESTADO
MALPAN DF MEXICO

ALBERTO CASTILLEJO MORAN
BOGOTA NO. 2383
GUADALAJARA, MEXICO

HOSPS DE MEXICO
DR. RUDOLFO STOTOMAYOR
MEXICO DF MEXICO

ROBERT TERAN G.
APARTADO 689
MANAGUA, NICARAGUA

UNCLASSIFIED

UNCLASSIFIED

PAGE 07 STATE 085278

CAJA DE SEGURO SOCIAL
PANAMA R PANAMA

CLINICAS HOSPITALES
PANAMA R DE PANAMA

HORACIO ICAZA AND CIA SA
LA CASA DEL MEDICO
APARTADO POSTAL 1689
PANAMA 1, PANAMA

AMERICAN HOSP SUPPLY
APARTADO 4436
LIMA, PERU

ASSOCIATED DRUGS INC.
P.O. BOX 3010
MANILA, P;ILIPPINES

LINOL MARKETING CORP
188 APO ST.
QUEZON CITY, PHILIPPINES

BOTICA BOIE, INC.
P. O. BOX 5081
(MAKATI P. O. D-711)
STATE CONDOMINIUM II,
AGUIRRE ST., LEGASNI VILLAGE
MAKATI, RIZAL, PHILIPPINES

IUNDINTER INTERCAMBIO
APARTADO 2761
LISBON, PORTUGAL

GUIDO RAYOS X
ALVAREZ QUINTERO

MADRID 4, SPAIN

SANKYO ENTERPRISES LTD.
P. O. BOX 22059
TAIPEI, TAIWAN
UNCLASSIFIED

UNCLASSIFIED

PAGE 08 STATE 085278

SHENG TUNG DEVELOP CO.
P. O. BOX 451
NO. 44 NEI CHIANG ST.
TAIPEI, TAIWAN

CESCO LTD.
P. O. BOX 445
BANGKOK, THAILAND

HACETTEPE UNIVERSITY
MEDICAL FACULTY
ANKARA, TURKEY

COLIMODIO S A
APARTADO 1053
CARACAS, VENEZUELA

AMERICAN HOSP SUPPLY
DE VENEZUELA CA
APARTADO 50950
CARACAS 105, VENEZUELA

SISCO

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 08 APR 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976STATE085278
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M D : AMS
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760134-0163
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1976/newtext/t19760481/aaaacrfe.tel
Line Count: 366
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 7
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: MartinML
Review Comment: n/a
Review Content Flags:
Review Date: 10 JUN 2004
Review Event:
Review Exemptions: n/a
Review History: RELEASED <10 JUN 2004 by SilvaL0>; APPROVED <04 JAN 2005 by MartinML>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
04 MAY 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - MANDATORY REQUIREMENT FOR INSTALLATION OF RELIEF VALVE IN ALL ANESTHESIA MACHINES
TAGS: OGEN, ETRD, TBIO, TW, TH, TU, AR, VE, CI, CO, CS, DR, EC, ES, FDA
To: BUENOS AIRES
MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006